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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/618,424 07/18/00 TAYA

Y 49979

EXAMINER

HM12/0925

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PADMANABHAN, K

ART UNIT	PAPER NUMBER
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1641

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DATE MAILED: 09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/618,424	TAYA ET AL.	
	Examiner Kartic Padmanabhan	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11 July 2001.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) 1,3,4 and 11-14 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 2,5-10 and 15 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-15 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> .	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group II, claims 2, 5-10, and 15 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Priority***

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Claim Objections***

5. Claims 5-6 and 8-10 are objected to because of the following informalities: the claims are dependent on non-elected claims. Appropriate correction is required. For purposes of this action, they are being treated as being dependent only on claim 2.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2, 5-10, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 2 recites the limitations "the activity" (lines 1-2), "the presence" (step a), "the detected amount" (step c), "the amount" (step c), and "the absence" (step c). There is insufficient antecedent basis for these limitations in the claim.

9. Claim 2 is further rejected as vague and indefinite because the wording of part c is unclear. First, since the whole recited method is a screening method, it is unclear what is meant by the screening recitation in part c. Isn't the process of screening being described in parts a and b? Applicant should reword the claim to better describe what is being claimed in part c. In addition, applicant should specify to what amount applicant is referring in line 16. Also, the recitation of decreasing the detected amount of acetyl group binding is vague and indefinite. Is the actual amount of binding being modulated, or simply the detected amount of binding?

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 2, 5-6, 9, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lill et al. (Nature, 1997). Lill et al. disclose that p300/CBP (which is considered to be an acetyltransferase) binds to p53 in the absence of viral oncoproteins. The reference also discloses that E1A disrupts binding of p300/CBP to p53 by binding to p300/CBP. The reference discloses the tagging of p53 with green fluorescent protein in a binding assay to show the binding of p300/CBP to p53. However, when E1A is cotransfected with GFP-P53 and epitope tagged p300, binding does not occur.

12. Claims 2, 5, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Scolnick et al. (Cancer Research, 1997). Scolnick et al. disclose the binding of CBP (an acetyltransferase) and p53. It was shown that CBP and P/CAF enhanced the ability of P53 to activate expression of p21<sup>cip1/waf1</sup>, while E1A and dominant negative CBP mutants suppressed p53-dependent p21<sup>cip1/waf1</sup> gene expression. To measure p53 transcriptional activity. P53 and p21<sup>cip1/waf1</sup> protein levels were by Western blotting using monoclonal antibodies.

13. Claims 2, 5-6, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Gu et al. (Cell, 1997). Gu et al. disclose that p53 is a substrate for p300 acetyltransferase. P53 was labeled by acetyl CoA, but labeling required the presence of both acetyl CoA and p300. The reference also discloses that bacterially produced p53 is inactive in DNA binding, but binding

can be activated by anti-p53 monoclonal antibody. Acetylation of p300 also dramatically increases the DNA-binding activity if fixed amounts of p53.

14. Claims 2, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Poethke et al. (J. Neuroimmun., 1997). The reference discloses the detection Choline acetyltransferase using ELISA, wherein peptide antibodies absorbed to the surface of polystyrene beads were used as the capture reagent. Monoclonal antibodies were then used to detect the immobilized acetyltransferase.

#### ***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lill et al. or Gu et al.

Lill et al. and Gu et al. teach acetyltransferase assays, as discussed above. However, neither of the references teaches the use of biotin to label the peptide substrate.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use biotin as a label with the methods of Lill et al. or Gu et al. because the biotin/avidin detection system, is very well known in the art and is commonly used for detection purposes.

### *Conclusion*

Claims 2, 5-10, and 15 are rejected.

References: Roth et al., Ghai et al., Hillman et al., Haugland et al., and Wainer et al. are cited as art of interest for teaching various acetyltransferase assays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Art Unit: 1641

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan  
Patent Examiner  
Art Unit 1641

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September 24, 2001



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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09/24/01